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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability MDL NO. 15-02641-PHX-DGC
Litigation

This Document Relates to:

WAYNE RUDEN,

Plaintiff,

v.

Case No. CV-16-00344-PHX-DGC

C. R. BARD, INC., a New Jersey
corporation, BARD PERIPHERAL
VASCULAR, INC., (a subsidiary and/or
division of defendant C. R. BARD, INC.),
an Arizona corporation, CALIFORNIA
PACIFIC MEDICAL CENTER, and DOES
1 to 100,

Defendants.

**DEFENDANTS C. R. BARD, INC. AND
BARD PERIPHERAL VASCULAR,
INC.'S ANSWER AND AFFIRMATIVE
DEFENSES AND DEMAND FOR
TRIAL BY JURY**

1 Defendants C. R. Bard, Inc. (“Bard”) and Bard Peripheral Vascular, Inc. (“BPV”)
2 (Bard and BPV are collectively “Defendants”) answer the First Amended Complaint
3 (“Plaintiff’s Complaint”) of Plaintiff Wayne Ruden (“Plaintiff”) as follows:

4 1. Defendants do not contest that Plaintiff brings this action against Defendants in
5 relation to an inferior vena cava filter. However, Defendants deny both that they are liable in
6 any manner to Plaintiff and that Plaintiff is entitled to recover damages in this case.
7 Defendants deny any remaining allegations contained in Paragraph 1 of Plaintiff’s Complaint.

8 2. Defendants do not contest that Plaintiff brings this action against Defendants.
9 However, Defendants deny both that they are liable in any manner to Plaintiff and that
10 Plaintiff is entitled to recover damages in this case. Defendants deny any remaining
11 allegations contained in Paragraph 2 of Plaintiff’s Complaint.

12 3. Defendants do not contest that Plaintiff brings this action against Defendants in
13 relation to an inferior vena cava filter. However, Defendants deny both that they are liable in
14 any manner to Plaintiff and that Plaintiff is entitled to recover damages in this case.
15 Defendants deny any remaining allegations contained in Paragraph 3 of Plaintiff’s Complaint.

16 **PARTIES**

17 4. Defendants lack knowledge or information sufficient to form a belief as to the
18 truth of the allegations regarding the citizenship and residency of Plaintiff and, on that basis,
19 deny them. Defendants deny the remaining allegations contained in Paragraph 4 of Plaintiff’s
20 Complaint.

21 5. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which
22 have not been and could not have been confirmed by Defendants, venue appears to be proper
23 in the United States District Court for the Northern District of California. Defendants admit
24 that they are authorized to do business, and do business, in the State of California. Defendants
25 lack knowledge or information sufficient to form a belief as to the truth of the allegations
26 regarding the remaining allegations contained in Paragraph 5 of Plaintiff’s Complaint and, on
27 that basis, deny them, including any allegations contained in Footnote 1.
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1 6. The allegations contained in Paragraph 6 of Plaintiff's Complaint are not
2 directed at Defendants and, as a result, require no response by Defendants. However, to the
3 extent Paragraph 6 purports to cast liability either directly or indirectly upon Defendants, said
4 Paragraph is expressly denied.

5 7. Defendants admit that they are authorized to do business, and do business, in
6 the State of California. Defendants deny the remaining allegations contained in Paragraph 7
7 of Plaintiff's Complaint.

8 8. Defendants deny that Bard is a Delaware corporation. Defendants admit that
9 Bard is a New Jersey Corporation with its principal place of business in New Jersey.
10 Defendants admit that Bard owns a facility where vena cava filters are manufactured,
11 including under the trademark Recovery® Filter System. Defendants admit that Bard is
12 authorized to do business, and does business, in the State of California. Defendants deny any
13 remaining allegations contained in Paragraph 8 of Plaintiff's Complaint.

14 9. Defendants admit that BPV is an Arizona Corporation. Defendants further
15 admit that BPV is a wholly owned subsidiary of Bard. Defendants also admit that BPV
16 designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed,
17 sold, marketed, and distributed filters under the trademark Recovery® Filter System.
18 Defendants admit that BPV is authorized to do business, and does business, in the State of
19 California. Defendants deny any remaining allegations contained in Paragraph 9 of Plaintiff's
20 Complaint.

21 10. The allegations contained in Paragraph 10 of Plaintiff's Complaint are not
22 directed toward Defendants and, as a result, require no response by Defendants. However, to
23 the extent Paragraph 10 purports to cast liability either directly or indirectly upon Defendants,
24 said Paragraph is expressly denied.

25 11. The allegations contained in Paragraph 11 of Plaintiff's Complaint are not
26 directed toward Defendants and, as a result, require no response by Defendants. However, to
27
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1 the extent Paragraph 11 purports to cast liability either directly or indirectly upon Defendants,
2 said Paragraph is expressly denied.

3 12. Defendants are without information or knowledge sufficient to form a belief as
4 to the truth of the allegations regarding the trade name of any inferior vena cava filter
5 implanted in Plaintiff and, on that basis, deny them. The remaining allegations contained in
6 Paragraph 12 of Plaintiff's Complaint are not directed toward Defendants and, as a result,
7 require no response by Defendants. However, to the extent Paragraph 12 purports to cast
8 liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

9 13. The allegations contained in Paragraph 13 of Plaintiff's Complaint are not
10 directed toward Defendants and, as a result, require no response by Defendants. However, to
11 the extent Paragraph 13 purports to cast liability either directly or indirectly upon Defendants,
12 said Paragraph is expressly denied.

13 14. Bard denies the allegations contained in Paragraph 14 of Plaintiff's Complaint.

14 **JURISDICTION AND VENUE**

15 15. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which
16 have not been and could not have been confirmed by Defendants, jurisdiction appears to be
17 proper in the United States District Court for the Northern District of California. However,
18 Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that
19 Plaintiff has suffered any damages whatsoever.

20 **GENERAL FACTUAL ALLEGATIONS**

21 16. Defendants deny the allegations contained in Paragraph 16 of Plaintiff's
22 Complaint.

23 17. Defendants admit that Bard owns a facility where vena cava filters are
24 manufactured, including under the trademark Recovery® Filter System. Defendants further
25 admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV
26 has designed, sold, marketed, and distributed filters under the trademark Recovery® Filter
27
28

1 System. Defendants deny any remaining allegations contained in Paragraph 17 of Plaintiff's
2 Complaint.

3 18. Defendants deny the allegations contained in Paragraph 18 of Plaintiff's
4 Complaint, including all sub-parts thereof.

5 19. Defendants are without knowledge or information sufficient to form a belief as
6 to the truth of the allegations regarding the trademark on any product at issue in this case and,
7 therefore, deny them. Defendants admit that Bard owns a facility where vena cava filters are
8 manufactured, including under the trademarks Recovery® and G2® Filter Systems.
9 Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava
10 filters and that BPV has designed, sold, marketed, and distributed filters under the trademarks
11 Recovery® and G2® Filter Systems. Defendants deny any remaining allegations contained in
12 Paragraph 19 of Plaintiff's Complaint.

13 20. Defendants lack knowledge or information sufficient to admit or deny the
14 allegation regarding the time frame when inferior vena cava filters were first introduced on
15 the market or the identity of manufacturers of inferior vena cava filters. Defendants deny any
16 remaining allegations of Paragraph 20 of Plaintiff's Complaint.

17 21. Defendants admit that inferior vena cava filters are intended to prevent injury or
18 death resulting from venous thrombosis and pulmonary embolism. Defendants further admit
19 that inferior vena cava filters may be designed for permanent placement, temporary
20 placement, or both. Defendants deny any remaining allegations contained in Paragraph 21 of
21 Plaintiff's Complaint.

22 22. Defendants admit that the inferior vena cava is a large vein that receives blood
23 from the lower regions of the body and delivers it to the right atrium of the heart. Defendants
24 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to
25 human health, including sometimes death. Defendants deny any remaining allegations
26 contained in Paragraph 22 of Plaintiff's Complaint.

1 23. Defendants admit that patients at an increased risk for developing deep vein
2 thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy,
3 including but not limited to the medications listed in Paragraph 23 of Plaintiffs' Complaint.
4 Defendants further admit that inferior vena cava filters may also be used to treat patients who
5 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants
6 lack knowledge or information sufficient to admit or deny any remaining allegations
7 contained in Paragraph 23 of Plaintiff's Complaint and, on that basis, deny them.

8 24. Defendants lack knowledge or information sufficient to admit or deny the
9 allegations regarding the medical community's concerns regarding the desirability of a
10 retrievable filter or the intent of manufacturers in general regarding the development of
11 retrievable filters. Defendants admit that the Recovery® Filter was cleared by the FDA for
12 permanent placement on November 27, 2002 and for retrievable placement on July 25, 2003,
13 pursuant to applications submitted under Section 510(k) of the Food, Drug and Cosmetic Act.
14 Defendants deny any remaining allegations of Paragraph 24 of Plaintiff's Complaint.

15 25. Defendants admit that the Recovery® Filter consists of shape-memory Nitinol
16 wires emanating from a central Nitinol sleeve. Defendants further admit that the twelve wires
17 form two levels of filtration for emboli: the legs provide the lower level of filtration, and the
18 arms provide the upper level of filtration. Defendants also admit that Nitinol contains "shape
19 memory." Defendants deny any remaining allegations contained in Paragraph 25 of Plaintiff's
20 Complaint.

21 26. Defendants deny the allegations contained in Paragraph 26 of Plaintiff's
22 Complaint.

23 27. Defendants deny the allegations contained in Paragraph 27 of Plaintiff's
24 Complaint.

25 28. Defendants deny the allegations contained in Paragraph 28 of Plaintiff's
26 Complaint.

1 29. Defendants admit that, as part of their continuing efforts to constantly evaluate
2 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
3 continually striving to improve the life-saving performance of those devices. The G2® Filter
4 was developed in furtherance of those efforts. Defendants deny the remaining allegations
5 contained in Paragraph 29 of Plaintiff's Complaint.

6 30. Defendants admit the G2® Filter System was cleared by the United States Food
7 and Drug Administration for permanent placement pursuant to an application submitted under
8 Section 510(k) of the Food, Drug and Cosmetic Act. Defendants admit that the G2® Filter
9 was originally cleared by the FDA in 2005. The allegations in Paragraph 30 of Plaintiff's
10 Complaint regarding the 510(k) process are conclusions of law that require no response. To
11 the extent a response to these allegations is required, Defendants deny these allegations.
12 Defendants deny any remaining allegations contained in Paragraph 30 of Plaintiff's
13 Complaint.

14 31. Defendants admit the G2® Filter System was cleared by the United States Food
15 and Drug Administration pursuant to an application submitted under Section 510(k) of the
16 Food, Drug and Cosmetic Act. Defendants admit that the G2® Filter was originally cleared
17 by the FDA for permanent use in 2005. Defendants further admit that the G2® Filter was
18 subsequently cleared by the FDA for optional use as a retrievable inferior vena cava filter in
19 2008. Defendants deny any remaining allegations contained in Paragraph 31 of Plaintiff's
20 Complaint.

21 32. Defendants deny the allegations contained in Paragraph 32 of Plaintiff's
22 Complaint, including all sub-parts thereof.

23 33. Defendants deny the allegations contained in Paragraph 33 of Plaintiff's
24 Complaint.

25 34. Defendants deny the allegations contained in Paragraph 34 of Plaintiff's
26 Complaint.

1 35. Defendants deny the allegations contained in Paragraph 35 of Plaintiff's
2 Complaint.

3 36. Defendants deny the allegations contained in Paragraph 36 of Plaintiff's
4 Complaint, including all sub-parts thereof.

5 37. Defendants deny the allegations contained in Paragraph 37 of Plaintiff's
6 Complaint.

7 38. Defendants deny the allegations contained in Paragraph 38 of Plaintiff's
8 Complaint.

9 39. Defendants deny the allegations contained in Paragraph 39 of Plaintiff's
10 Complaint.

11 40. Defendants deny the allegations contained in Paragraph 40 of Plaintiff's
12 Complaint.

13 41. Defendants deny the allegations contained in Paragraph 41 of Plaintiff's
14 Complaint.

15 42. Defendants admit that there are various well-documented complications that
16 may occur as a result of complications with any inferior vena cava filter. Defendants further
17 admit that it is well documented that many instances of complications with inferior vena cava
18 filters result in no symptoms whatsoever. By way of further response, Defendants state that
19 there are incidents related to the occurrence of known complications associated with every
20 manufacturer of inferior vena cava filters. Defendants deny any remaining allegations of
21 Paragraph 42 of Plaintiff's Complaint.

22 43. Defendants deny the allegations contained in Paragraph 43 of Plaintiff's
23 Complaint.

24 44. Defendants deny the allegations contained in Paragraph 44 of Plaintiff's
25 Complaint, including all subparts thereof.

26 45. Defendants deny the allegations contained in Paragraph 45 of Plaintiff's
27 Complaint, including all sub-parts thereof.

46. Defendants deny the allegations contained in Paragraph 46 of Plaintiff's Complaint.

47. The allegations contained in Paragraph 47 of Plaintiff's Complaint are not directed at Defendants and, as a result, require no response by Defendants. However, to the extent Paragraph 47 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

48. Defendants deny the allegations contained in Paragraph 48 of Plaintiff's Complaint.

FIRST CAUSE OF ACTION

NEGLIGENCE (BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)

49. Defendants incorporate by reference their responses to Paragraphs 1-48 of Plaintiff's Complaint as if fully set forth herein.

50. Defendants admit that Bard owns a facility where vena cava filters are manufactured, including under the trademarks Recovery® Filter Systems. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademarks Recovery® Filter Systems. Defendants deny any remaining allegations contained in Paragraph 50 of Plaintiff's Complaint.

51. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, therefore, deny them. Defendants deny any remaining allegations contained in Paragraph 51 of Plaintiff's Complaint.

52. The allegations contained in Paragraph 52 of Plaintiff's Complaint regarding Defendants' duty are conclusions of law, to which no response is required. To the extent a response is required, Defendants deny those allegations.

53. Defendants deny the allegations contained in Paragraph 53 of Plaintiff's Complaint.

54. Defendants deny the allegations contained in Paragraph 54 of Plaintiff's Complaint, including all subparts thereof.

55. Defendants deny the allegations contained in Paragraph 55 of Plaintiff's Complaint.

56. Defendants deny the allegations contained in Paragraph 56 of Plaintiff's Complaint.

57. Defendants deny the allegations contained in Paragraph 57 of Plaintiff's Complaint, including all sub-parts thereof.

58. Defendants deny the allegations contained in Paragraph 58 of Plaintiff's Complaint.

59. Defendants deny the allegations contained in Paragraph 59 of Plaintiff's Complaint.

SECOND CAUSE OF ACTION

NEGLIGENCE (CPMC AND DOES 1-100 INCLUSIVE)

60. Defendants incorporate by reference their responses to Paragraphs 1-59 of Plaintiff's Complaint as if fully set forth herein.

61. The allegations contained in Paragraph 61 of Plaintiff's Complaint are not directed to Defendants and, therefore, require no response. To the extent a response is required, Defendants deny those allegations.

62. The allegations contained in Paragraph 62 of Plaintiff's Complaint are not directed to Defendants and, therefore, require no response. To the extent a response is required, Defendants deny those allegations.

63. The allegations contained in Paragraph 63 of Plaintiff's Complaint are not directed to Defendants and, therefore, require no response. To the extent a response is required, Defendants deny those allegations.

64. The allegations contained in Paragraph 64 of Plaintiff's Complaint are not directed to Defendants and, therefore, require no response. To the extent a response is required, Defendants deny those allegations.

65. The allegations contained in Paragraph 65 of Plaintiff's Complaint are not directed to Defendants and, therefore, require no response. To the extent a response is required, Defendants deny those allegations.

66. The allegations contained in Paragraph 66 of Plaintiff's Complaint are not directed to Defendants and, therefore, require no response. To the extent a response is required, Defendants deny those allegations.

67. The allegations contained in Paragraph 67 of Plaintiff's Complaint are not directed to Defendants and, therefore, require no response. To the extent a response is required, Defendants deny those allegations.

68. The allegations contained in Paragraph 68 of Plaintiff's Complaint are not directed to Defendants and, therefore, require no response. To the extent a response is required, Defendants deny those allegations.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)

69. Defendants incorporate by reference their responses to Paragraphs 1-68 of Plaintiff's Complaint as if fully set forth herein.

70. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, therefore, deny them. Defendants admit that Bard owns a facility where vena cava filters are manufactured, including under the trademarks Recovery® Filter Systems. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the

1 trademarks Recovery® Filter Systems. Defendants deny any remaining allegations contained
2 in Paragraph 70 of Plaintiff's Complaint.

3 71. Defendants deny the allegations contained in Paragraph 71 of Plaintiff's
4 Complaint.

5 72. Defendants deny the allegations contained in Paragraph 72 of Plaintiff's
6 Complaint.

7 73. The allegations contained in Paragraph 73 of Plaintiff's Complaint regarding
8 Defendants' duty are conclusions of law, to which no response is required. To the extent a
9 response is required, however, Defendants deny these allegations.

10 74. Defendants deny the allegations contained in Paragraph 74 of Plaintiff's
11 Complaint.

12 75. Defendants deny the allegations contained in Paragraph 75 of Plaintiff's
13 Complaint.

14 76. Defendants deny the allegations contained in Paragraph 76 of Plaintiff's
15 Complaint.

16 77. Defendants deny the allegations contained in Paragraph 77 of Plaintiff's
17 Complaint.

18 78. Defendants deny the allegations contained in Paragraph 78 of Plaintiff's
19 Complaint.

20 79. Defendants deny the allegations contained in Paragraph 79 of Plaintiff's
21 Complaint.

22 80. Defendants deny the allegations contained in Paragraph 80 of Plaintiff's
23 Complaint.

24 81. Defendants deny the allegations contained in Paragraph 81 of Plaintiff's
25 Complaint.

FOURTH CAUSE OF ACTION

**STRICT PRODUCTS LIABILITY – DESIGN DEFECT – CONSUMER
EXPECTATION (BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)**

82. Defendants incorporate by reference their responses to Paragraphs 1-81 of Plaintiff's Complaint as if fully set forth herein.

83. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Recovery® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Recovery® Filter System. Defendants deny any remaining allegations contained in Paragraph 83 of Plaintiff's Complaint.

84. Defendants deny the allegations contained in Paragraph 84 of Plaintiff's Complaint.

85. Defendants deny the allegations contained in Paragraph 85 of Plaintiff's Complaint.

86. Defendants deny the allegations contained in Paragraph 86 of Plaintiff's Complaint.

87. Defendants deny the allegations contained in Paragraph 87 of Plaintiff's Complaint.

88. Defendants deny the allegations contained in Paragraph 88 of Plaintiff's Complaint.

89. Defendants deny the allegations contained in Paragraph 89 of Plaintiff's Complaint.

FIFTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECT – RISK-BENEFIT TEST

(BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)

90. Defendants incorporate by reference their responses to Paragraphs 1-89 of Plaintiff's Complaint as if fully set forth herein.

91. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Recovery® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Recovery® Filter System. Defendants deny any remaining allegations contained in Paragraph 91 of Plaintiff's Complaint.

92. Defendants deny the allegations contained in Paragraph 92 of Plaintiff's Complaint.

93. Defendants deny the allegations contained in Paragraph 93 of Plaintiff's Complaint.

94. Defendants deny the allegations contained in Paragraph 94 of Plaintiff's Complaint.

95. Defendants deny the allegations contained in Paragraph 95 of Plaintiff's Complaint.

96. Defendants deny the allegations contained in Paragraph 96 of Plaintiff's Complaint.

97. Defendants deny the allegations contained in Paragraph 97 of Plaintiff's Complaint.

SIXTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)

98. Defendants incorporate by reference their responses to Paragraphs 1-97 of Plaintiff's Complaint as if fully set forth herein.

99. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Recovery® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Recovery® Filter System. Defendants deny any remaining allegations contained in Paragraph 99 of Plaintiff's Complaint.

100. Defendants deny the allegations contained in Paragraph 100 of Plaintiff's Complaint.

101. Defendants deny the allegations contained in Paragraph 101 of Plaintiff's Complaint.

102. Defendants deny the allegations contained in Paragraph 102 of Plaintiff's Complaint.

103. Defendants deny the allegations contained in Paragraph 103 of Plaintiff's Complaint.

SEVENTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

(BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)

104. Defendants incorporate by reference their responses to Paragraphs 1-104 of Plaintiff's Complaint as if fully set forth herein.

1 105. Defendants deny the allegations contained in Paragraph 105 of Plaintiff's
2 Complaint, including all subparts thereof.

3 106. Defendants deny the allegations contained in Paragraph 106 of Plaintiff's
4 Complaint.

5 107. Defendants deny the allegations contained in Paragraph 107 of Plaintiff's
6 Complaint.

7 108. Defendants deny the allegations contained in Paragraph 108 of Plaintiff's
8 Complaint.

9 109. Defendants deny the allegations contained in Paragraph 109 of Plaintiff's
10 Complaint.

11 110. Defendants deny the allegations contained in Paragraph 110 of Plaintiff's
12 Complaint.

13 111. Defendants deny the allegations contained in Paragraph 111 of Plaintiff's
14 Complaint.

15 112. Defendants deny the allegations contained in Paragraph 112 of Plaintiff's
16 Complaint.

17 113. Defendants deny the allegations contained in Paragraph 113 of Plaintiff's
18 Complaint.

19 114. Defendants deny the allegations contained in Paragraph 114 of Plaintiff's
20 Complaint.

21 **EIGHTH CAUSE OF ACTION**

22 **BREACH OF FIDUCIARY DUTY**

23 **(CPMC AND DOES 1-100 INCLUSIVE)**

24 115. Defendants incorporate by reference their responses to Paragraphs 1-114 of
25 Plaintiff's Complaint as if fully set forth herein.

1 116. The allegations contained in Paragraph 116 of Plaintiff's Complaint are not
2 directed to Defendants and, therefore, require no response. To the extent a response is
3 required, Defendants deny those allegations.

4 117. The allegations contained in Paragraph 117 of Plaintiff's Complaint are not
5 directed to Defendants and, therefore, require no response. To the extent a response is
6 required, Defendants deny those allegations.

7 118. The allegations contained in Paragraph 118 of Plaintiff's Complaint are not
8 directed to Defendants and, therefore, require no response. To the extent a response is
9 required, Defendants deny those allegations.

10 119. The allegations contained in Paragraph 119 of Plaintiff's Complaint are not
11 directed to Defendants and, therefore, require no response. To the extent a response is
12 required, Defendants deny those allegations.

13 120. The allegations contained in Paragraph 120 of Plaintiff's Complaint are not
14 directed to Defendants and, therefore, require no response. To the extent a response is
15 required, Defendants deny those allegations.

16 121. The allegations contained in Paragraph 121 of Plaintiff's Complaint are not
17 directed to Defendants and, therefore, require no response. To the extent a response is
18 required, Defendants deny those allegations.

19 122. The allegations contained in Paragraph 122 of Plaintiff's Complaint are not
20 directed to Defendants and, therefore, require no response. To the extent a response is
21 required, Defendants deny those allegations.

22 123. The allegations contained in Paragraph 123 of Plaintiff's Complaint are not
23 directed to Defendants and, therefore, require no response. To the extent a response is
24 required, Defendants deny those allegations.

NINTH CAUSE OF ACTION

NEGLIGENCE – RECALL/RETROFIT

(ALL DEFENDANTS AND DOES 1-100 INCLUSIVE)

124. Defendants incorporate by reference their responses to Paragraphs 1-123 of Plaintiff's Complaint as if fully set forth herein.

125. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Recovery® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Recovery® Filter System. Defendants deny any remaining allegations contained in Paragraph 125 of Plaintiff's Complaint.

126. Defendants deny the allegations contained in Paragraph 126 of Plaintiff's Complaint.

127. Bard admits that on August 9, 2010, the Food and Drug Administration posted an initial communication titled "Inferior Vena Cava (IVC) Filters: Initial Communication: Risk of Adverse Events with Long Term Use," and that Initial Communication stated that "Since 2005, the FDA has received 921 device adverse event reports involving IVC filters." However, to the extent Paragraph 127 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied. Bard denies any remaining allegations contained in Paragraph 127 of Plaintiff's Complaint.

128. The allegations contained in Paragraph 128 of Plaintiff's Complaint are not directed at Defendants and, therefore, require no response. To the extent a response is required, Defendants deny these allegations.

129. Defendants deny that the Recovery® Filter is unreasonably dangerous or defective in any manner. Defendants deny the remaining allegations contained in Paragraph 129 of Plaintiff's Complaint, as stated.

1 130. Defendants deny the allegations contained in Paragraph 130 of Plaintiff's
2 Complaint.

3 131. Defendants deny the allegations contained in Paragraph 131 of Plaintiff's
4 Complaint.

5 132. Defendants deny the allegations contained in Paragraph 132 of Plaintiff's
6 Complaint.

7 133. Defendants deny the allegations contained in Paragraph 133 of Plaintiff's
8 Complaint.

9 134. Defendants deny the allegations contained in Paragraph 134 of Plaintiff's
10 Complaint.

11 **PUNITIVE DAMAGES ALLEGATIONS**

12 **(ALL DEFENDANTS AND DOES 1-100 INCLUSIVE)**

13 135. Defendants incorporate by reference their responses to Paragraphs 1-134 of
14 Plaintiff's Complaint as if fully set forth herein.

15 136. Defendants deny the allegations contained in Paragraph 136 of Plaintiff's
16 Complaint.

17 137. Defendants deny the allegations contained in Paragraph 137 of Plaintiff's
18 Complaint.

19 138. Defendants deny the allegations contained in Paragraph 138 of Plaintiff's
20 Complaint, including all sub-parts thereof.

21 139. Defendants deny the allegations contained in Paragraph 139 of Plaintiff's
22 Complaint.

23 140. Defendants deny the allegations contained in Paragraph 140 of Plaintiff's
24 Complaint.

25 141. Defendants deny the allegations contained in Paragraph 141 of Plaintiff's
26 Complaint.

1 Furthermore, responding to the unnumbered Paragraph, including sub-parts thereof,
2 labeled "PRAYER FOR DAMAGES" and beginning "WHEREFORE," Defendants deny the
3 allegations contained in such Paragraph, including all sub-parts thereof.

4 Defendants further deny each and every allegation not specifically admitted herein.

5 **DEFENSES**

6 Defendants allege as affirmative defenses the following:

7 1. Plaintiff's Complaint filed herein fails to state a claim or claims upon which
8 relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

9 2. The sole proximate cause of Plaintiff's damages, if any were sustained, was the
10 negligence of a person or persons or entity for whose acts or omissions Defendants were and
11 are in no way liable.

12 3. If Plaintiff has been damaged, which Defendants deny, any recovery by
13 Plaintiff is barred to the extent Plaintiff voluntarily exposed himself to a known risk and/or
14 failed to mitigate his alleged damages. To the extent Plaintiff has failed to mitigate his alleged
15 damages, any recovery shall not include alleged damages that could have been avoided by
16 reasonable care and diligence.

17 4. Plaintiff failed to exercise ordinary care for her own safety such that Plaintiff is
18 not entitled to recover.

19 5. The injuries and damages allegedly sustained by Plaintiff may be due to the
20 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff,
21 over which Defendants had no control.

22 6. Plaintiff's causes of action may be barred by the applicable statute of
23 limitations and/or statute of repose.

24 7. Plaintiff's claims are barred, in whole or in part, by the doctrines of laches,
25 waiver, and/or estoppel.

26 8. There was no defect in the product at issue with the result that Plaintiff is not
27 entitled to recover against Defendants.

1 9. There was no causal connection between any alleged defect in the product at
2 issue and Plaintiff's alleged damages with the result that Plaintiff is not entitled to recover
3 against Defendants.

4 10. If Plaintiff has been damaged, which Defendants deny, such damages were
5 caused by the negligence or fault of Plaintiff.

6 11. If Plaintiff has been damaged, which Defendants deny, such damages were
7 caused by the negligence or fault of persons and/or entities for whose conduct Defendants are
8 not legally responsible.

9 12. If Plaintiff suffered any damages or injuries, which are denied, Defendants state
10 that Plaintiff's recovery is barred, in whole or in part, or subject to reduction under the
11 doctrines of contributory and/or comparative negligence.

12 13. In the further alternative, and only in the event that it is determined that
13 Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to
14 the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff,
15 any other defendants, third-party defendants, or other persons, including any party immune
16 because bankruptcy renders them immune from further litigation, as well as any party, co-
17 defendant, or non-parties with whom Plaintiff has settled or may settle in the future.

18 14. The trier of fact should apportion its award of damages among the persons who
19 are liable according to the degree of fault of each person.

20 15. If Plaintiff has been damaged, which Defendants deny, the negligence or fault
21 of Plaintiff constitutes the sole, intervening, and superseding cause of Plaintiff's alleged
22 damages.

23 16. If Plaintiff has been damaged, which Defendants deny, the negligence or fault
24 of persons and/or entities for whose conduct Defendants are not legally responsible
25 constitutes the sole, intervening, and superseding cause of Plaintiff's alleged damages.

26 17. If Plaintiff has been damaged, which Defendants deny, the actions of persons or
27 entities for whose conduct Defendants are not legally responsible and the independent
28

1 knowledge of these persons or entities of the risks inherent in the use of the product and other
2 independent causes, constitute an intervening and superseding cause of Plaintiff's alleged
3 damages.

4 18. If Plaintiff has been damaged, which Defendants deny, such damages were
5 caused by unforeseeable, independent, intervening, and/or superseding events for which
6 Defendants are not legally responsible.

7 19. If Plaintiff has been damaged, which Defendants deny, such damages were
8 caused by abuse, misuse, user error and/or modification of the product at issue for which
9 Defendants were and are in no way liable.

10 20. Defendants made no warranties of any kind, express or implied, including any
11 alleged implied warranty of merchantability or implied warranty of fitness for a particular
12 purpose, or any representations of any nature whatsoever to Plaintiff. To the extent
13 applicable, Plaintiff's breach of warranty claims are barred by a lack of privity between
14 Plaintiff and Defendants. To the extent Plaintiff make warranty claims, whether express or
15 implied, the claims are barred or limited by any and all express conditions or disclaimers, by
16 Plaintiff's lack of reliance on any such warranties, and by waiver.

17 21. Plaintiff's claims for breach of implied warranty must fail because the product
18 was not used for its ordinary purpose.

19 22. Plaintiff's claim for breach of warranty is barred because Plaintiff did not first
20 give notice of any alleged defect of the product to Defendants.

21 23. Defendants neither had nor breached any alleged duty to warn with respect to
22 the product, with the result that Plaintiff is not entitled to recover.

23 24. Plaintiff's failure to warn claims are barred by virtue of the intervention of the
24 learned intermediary or intermediaries to whom Defendants discharged their duties to warn.

25 25. The conduct of Defendants and the subject product at all times conformed with
26 the Federal Food, Drug and Cosmetic Act, and other pertinent federal statutes and
27 regulations. Accordingly, Plaintiff's claims are barred, in whole or in part, under the doctrine
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1 of federal preemption, and granting the relief requested would impermissibly infringe upon
2 and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause
3 of the United States Constitution.

4 26. If Plaintiff recovers from Defendants, Defendants are entitled to contribution,
5 set-off, and/or indemnification, either in whole or in part, from all persons or entities whose
6 negligence or fault proximately caused or contributed to cause Plaintiff's alleged damages.

7 27. Plaintiff's claims are, or may be, barred, in whole or in part, to the extent that
8 Plaintiff has released, settled with, entered into an accord and satisfaction, or otherwise
9 compromised their claims. Defendants are entitled to a set-off for the entire amount of
10 proceeds Plaintiff has, or may, recover from all other sources.

11 28. Should Defendants be held liable to Plaintiff, which liability is specifically
12 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff
13 from all collateral sources.

14 29. Defendants assert any and all defenses, claims, credits, offsets, or remedies
15 provided by the Restatements (Second and Third) of Torts and reserve the right to amend
16 their Answer to file such further pleadings as are necessary to preserve and assert such
17 defenses, claims, credits, offsets, or remedies.

18 30. The device at issue was not sold in a defective condition unreasonably
19 dangerous to the user or consumer, and therefore Plaintiff's claims are barred under the
20 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and
21 comparable provisions of the Restatement (Third) of Torts (Products Liability).

22 31. Plaintiff's claims are barred because the methods, standards, warnings, and
23 instructions used in manufacturing and/or marketing the product at issue conformed with the
24 generally recognized, reasonably available, and reliable state of knowledge when the product
25 was manufactured and marketed.

26 32. Plaintiff's claims are barred because the methods, standards, warnings, and
27 instructions used in manufacturing and/or marketing the product at issue conformed to
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1 industry custom/usage standards and/or legislative, administrative, and/or regulatory
2 standards.

3 33. At all relevant times during which the device at issue was designed, developed,
4 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
5 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
6 information, and instructions, all pursuant to generally recognized prevailing industry
7 standards and state-of-the-art in existence at the time.

8 34. The design complained of in Plaintiff's Complaint, the alleged defects of the
9 product, and/or any alternative design claimed by Plaintiff were not known and, in light of the
10 existing, reasonably-available scientific and technological knowledge, could not have been
11 known at the time the product at issue was designed, manufactured, and sold. Any alleged
12 alternative design was not scientifically or technologically feasible or economically practical.

13 35. Defendants specifically plead all affirmative defenses under the Uniform
14 Commercial Code ("UCC") now existing or which may arise in the future, including those
15 defenses provided by UCC §§ 2-607 and 2-709.

16 36. No act or omission of Defendants was malicious, willful, wanton, reckless, or
17 grossly negligent, and, therefore, any award of punitive damages is barred.

18 37. In response to Plaintiff's demand for punitive damages, Defendants specifically
19 incorporate by reference any and all standards of limitations regarding the determination
20 and/or enforceability of punitive damages awards that arose in the decisions of *BMW of*
21 *No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool*
22 *Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct.
23 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S.
24 June 25, 2008) and their progeny as well as other similar cases under both federal and state
25 law.

38. Plaintiff's claim for punitive damages is in contravention of the rights of Defendants under the following provisions of the United States Constitution and analogous provisions of the California Constitution:

Plaintiff's claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America on grounds including the following:

- (a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiff satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;
- (b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;
- (c) the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- (d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- (e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate

the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;

(h) the award of punitive damages to the plaintiff in this action would constitute a deprivation of property without due process of law; and

(i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

39. This case may be subject to dismissal or transfer under the doctrine of *forum non conveniens*.

40. The device at issue complied with any applicable product safety statute or administrative regulation, and therefore Plaintiff's defective design and warnings-based claims are barred under the Restatement (Third) of Torts: Products Liability § 4, et seq. and comments thereto.

41. To the extent Plaintiff's Complaint alleges misrepresentation or fraud, these allegations do not comply with the requisite of particularity under applicable procedural rules and/or law.

42. Plaintiff's claims are barred because there was insufficiency of process and/or insufficiency of service of process.

1 Defendants intend to rely upon any additional affirmative defenses under California
2 law that become available during the course of investigation and/or discovery and reserves
3 the right to amend its Answer to assert these defenses.

4 **REQUEST FOR JURY TRIAL**

5 Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury
6 on all issues appropriate for jury determination.

7 **WHEREFORE**, Defendants aver that Plaintiff is not entitled to the relief demanded in
8 the Plaintiff's Complaint, and these Defendants, having fully answered, pray that this action
9 against them be dismissed and that they be awarded their costs in defending this action and
10 that they be granted such other and further relief as the Court deems just and appropriate.

11 This 23rd day of February, 2016.

12
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24 **Bard Peripheral Vascular, Inc.**

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 23, 2016, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

s/Richard B. North, Jr.
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